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8 **UNITED STATES DISTRICT COURT**
9 **NORTHERN DISTRICT OF CALIFORNIA**
10 **SAN FRANCISCO DIVISION**

11
12 **RAYMOND J. COLLETTE,**

13 Plaintiff,

14 v.

15 **WYETH PHARMACEUTICALS INC;**
16 **SANDOZ PHARMACEUTICALS**
CORPORATION D/B/A SANDOZ,
17 **INC.; NOVARTIS**
PHARMACEUTICALS
18 **CORPORATION; AND EON LABS,**
INC., F/K/A EON LABS
19 **MANUFACTURING, INC.,**

20 Defendants.

CASE NO. 3:16-cv-01034-JD

DEFENDANT WYETH
PHARMACEUTICALS INC.'S NOTICE OF
MOTION AND MOTION TO DISMISS
THIRD AMENDED COMPLAINT AND
MEMORANDUM OF POINTS AND
AUTHORITIES IN SUPPORT THEREOF

F.R.C.P. 12(b)(6)

Date: August 29, 2019
Time: 10:00 AM
Judge: Hon. James Donato
Courtroom: 11, 19th Floor

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NOTICE OF MOTION AND MOTION TO DISMISS

PLEASE TAKE NOTICE that on August 29, 2019, at 10:00 a.m., or as soon thereafter as the matter may be heard before the Honorable Judge James Donato, in the United States District Court for the Northern District of California, Courtroom 11, 19th Floor, United States Courthouse, 450 Golden Gate Avenue, San Francisco, California, Defendant Wyeth Pharmaceuticals Inc. will and hereby does move the court to dismiss the Third Amended Complaint (“TAC”) pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

In the Court’s June 25, 2019 Order re Motions to Dismiss (“Order”), Dkt. 93, the Court granted Plaintiff “one last chance” to amend his allegations and claims for off-label marketing. *See* Order at 4. The Court has dismissed, with prejudice, Plaintiff’s claims for inadequate warnings and labeling and for failure to provide the Medication Guide. The Order expressly limited any amended complaint to “claims based on [Plaintiff’s] off-label marketing allegations only,” and prohibited Plaintiff from “amend[ing] or re-alleg[ing] his previously dismissed claims” or “add[ing] any new claims or defendants without express leave of Court.” Order at 4. The Court further ordered that “[f]ailure to amend by the deadline in a manner consistent with the Court’s order will result in a dismissal under Federal Rule of Civil Procedure 41(b).” *Id.*

The TAC should be fully and finally dismissed, with prejudice, because (1) it violates the express limitations and prohibitions of the Order by re-pleading dismissed allegations and pleading a new cause of action without leave of Court, and (2) Plaintiff’s off-label marketing allegations still fail to state a claim because they do not satisfy the plausibility and particularity requirements of Rules 8(a) and 9(b).

This motion is based on this Notice of Motion and Motion to Dismiss, the accompanying Memorandum of Points and Authorities, the pleadings and papers filed herein, and the argument of counsel at the time of any hearing.

Dated: July 24, 2019

DLA PIPER LLP (US)

By /s/ George Gigounas
 GEORGE GIGOUNAS
 Attorneys for Defendant
 Wyeth Pharmaceuticals Inc.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION AND STATEMENT OF ISSUES TO BE DECIDED

The Third Amended Complaint (“TAC”) is Plaintiff’s¹ fourth attempt to state a viable claim against Wyeth for alleged misconduct relating to its marketing and promotion of Cordarone® (the brand-name equivalent of the generic amiodarone Plaintiff was prescribed by his physician). The Court has twice dismissed Plaintiff’s complaint, with “limited” leave to amend. *See* Dkt. 93 at 1. The only claim the Court allowed to proceed was an off-label-promotion-based theory, and the Court expressly instructed Plaintiff that any amendment must include specific facts about what “each defendant said and did, and how those statements and actions (or lack thereof) relate[d] to plaintiff personally and to his physician.” *Id.* at 3-4 (alteration in original). Plaintiff has not done that. The Court should now dismiss Plaintiff’s claim with prejudice because the TAC still “wholly fail[s],” *id.*, to allege any specific facts that would tie Wyeth’s alleged conduct to Plaintiff’s alleged injuries. Like Plaintiff’s previous efforts, the TAC fails to state a claim against Wyeth that is plausible on its face or that satisfies the heightened pleading requirements for a claim sounding in fraud, and thus should be dismissed—this time with prejudice.

When the Court dismissed Plaintiff’s Second Amended Complaint (“SAC”) for failure to state a claim and granted Plaintiff “one more chance” to plead certain limited allegations related to off-label marketing, the Order was explicit that Plaintiff’s claims for inadequate warnings and failure to provide the Medication Guide were dismissed *with prejudice* and could not be re-alleged in any amended complaint, which had to be limited to “claims based on his off-label marketing allegations *only*.” *See* Order re Motions to Dismiss (“Order”), Dkt. 93, at 4 (emphasis added). The Order also expressly prohibited Plaintiff from adding any new claims “without express leave of Court.” *Id.* Any amendment not “consistent with the Court’s order [would] result

¹ The TAC states that “[a] Motion to Substitute Jeanne Collette, as Personal Representative and Executrix of the Estate of Raymond Collette as named Plaintiff will be filed contemporaneously with this Amended Complaint or shortly thereafter.” *See* TAC at 1 n.1. As of the date of this filing, no such motion has been filed. The term “Plaintiff” in this motion refers interchangeably to Decedent Raymond Collette and to any substitute Plaintiff.

1 in a dismissal under Federal Rule of Civil Procedure 41(b).” *Id.*

2 Plaintiff’s TAC violates the Court’s express limitations on the scope of permissible
3 amendment. This violation alone warrants dismissal with prejudice. In addition to improperly re-
4 pleading claims and allegations for inadequate warnings and failure to provide the Medication
5 Guide, the TAC also adds a wholly new claim for “Strict Liability – Manufacturing Defect,” for
6 which Plaintiff did not seek or obtain “express leave of Court,” and which improperly echoes
7 those previously-dismissed claims. Order at 4. Because these amendments are not consistent with
8 the Court’s Order, the TAC should be dismissed under Fed. R. Civ. P. 41(b). *Id.*

9 Even putting aside Plaintiff’s violations of the Order, Plaintiff still has failed to state an
10 off-label marketing claim against Wyeth. Rather, the TAC suffers from the same deficiencies and
11 overgeneralized allegations as the previously dismissed complaints. Plaintiff still fails to
12 articulate “‘what, specifically, each defendant said and did and how those statements and actions
13 (or lack thereof) relate[d] to plaintiff personally and to his physician,’” and does not “adequately
14 allege facts for each element of his claims against each defendant for the off-label marketing
15 portion of his case.” Order at 3-4 (quoting order dismissing SAC, Dkt. 76 at 4). Instead, Plaintiff
16 relies on the same generalized assertions regarding decades-old FDA enforcement actions and the
17 general drug approval process without tying those allegations “in any concrete way to himself
18 ‘and/or his prescribing physician.’” Order at 4.

19 The Court should now dismiss Plaintiff’s action for good. After multiple rounds of
20 pleading and opportunities to amend, it is plain that Plaintiff cannot state a viable claim against
21 Wyeth, has no specific allegations to tie together Wyeth’s alleged conduct and Plaintiff’s alleged
22 injuries, and has not followed the Court’s express instructions and orders. Any further amendment
23 would be futile, and dismissal this time should be final and with prejudice.

24 **II. BACKGROUND**

25 **A. Wyeth Pharmaceuticals Inc.**

26 Wyeth originally brought the prescription medication amiodarone to market in the United
27 States in 1984. Amiodarone is prescribed to treat arrhythmias—irregular heartbeats. Wyeth
28 marketed the drug under the brand name Cordarone®. In 1998, the first generic version of

1 amiodarone was approved and distributed, and today, several companies manufacture and sell
 2 generic amiodarone in the United States. Wyeth ceased marketing of Cordarone® in the late
 3 1990's and stopped selling it in 2015.

4 **B. Plaintiff and His Claims**

5 Plaintiff alleges he was prescribed and began taking a generic version of amiodarone
 6 manufactured and distributed by Defendants Sandoz and Eon in January 2012 after receiving a
 7 diagnosis of non-life-threatening atrial fibrillation (“A-fib”), a common form of arrhythmia. *E.g.*,
 8 TAC ¶¶ 22-23; *see also* SAC, Dkt. 77, ¶¶ 29-30. Plaintiff alleges his physician “was a victim of
 9 Defendant Wyeth’s long term and successful brand innovator promotional efforts as well as
 10 Sandoz/Eon’s sales efforts that failed to disclose the details and dangers of Amiodarone toxicity
 11 related to its use for treating atrial fibrillation.” TAC ¶¶ 23, 30; *see also* SAC ¶ 30. These efforts
 12 are alleged to have “materially affected [his physician’s] decision to prescribe Amiodarone to
 13 Decedent and Decedent’s decision to take it.” TAC ¶ 23; *see also* SAC ¶ 30. Plaintiff alleges that
 14 as a proximate result of his use of amiodarone, he developed “amiodarone-induced pulmonary
 15 fibrosis.” TAC ¶ 1. In his original complaint, Plaintiff alleged more specifically that he was
 16 “discharged with a diagnosis of amiodarone-induced pulmonary fibrosis” in September 2012,
 17 after a month in the hospital. Compl. ¶ 37.

18 Plaintiff has alleged that Defendants, including Wyeth, engaged in off-label promotion by
 19 marketing the drug for unapproved uses, failed to ensure that Plaintiff received a federally-
 20 mandated Medication Guide with his general amiodarone prescription, and otherwise failed to
 21 provide or ensure adequate warnings and drug labeling, all of which allegedly caused his injuries.
 22 In its March 12, 2018 Order re Motions to Dismiss as to the First Amended Complaint (“FAC”),
 23 the Court held that Plaintiff’s claims for inadequate warnings were preempted and dismissed all
 24 such allegations with prejudice but granted Plaintiff leave to amend his Medication Guide and
 25 off-label promotion claims. *See* Dkt. 76.

26 Defendants again moved to dismiss because the SAC failed to cure the pleading
 27 deficiencies identified by the Court. In its June 25, 2019 Order granting that motion “with a
 28 limited and likely final opportunity to amend,” the Court reiterated that allegations relating to the

adequacy of warnings or labels “have already been dismissed and are not properly before the Court.” Order at 2. The Court also dismissed Plaintiff’s Medication Guide claims “without a further opportunity to amend” both because Plaintiff failed to supply “any of the additional factual detail called for by the Court” and because the claim is “based on federal regulatory duties only,” and therefore preempted. *Id.* at 3.

The Court found that Plaintiff also “wholly failed” to provide the specific allegations necessary to state a claim for off-label promotion and that those claims did not meet the requirements of *Twombly*, *Iqbal*, Rule 8(a), and Rule 9(b). Order at 4. Nevertheless, the Court granted Plaintiff “one last chance to amend these allegations and claims only.” *Id.* The Order was clear that all other claims should be removed from any amended pleading, and no additional claims could be alleged without express leave of Court.

Plaintiff filed the TAC on July 10, 2019. As described below, the TAC is defective for the same reasons as before. Plaintiff still has not pleaded any particular facts that would show how Wyeth’s alleged conduct allegedly caused Plaintiff’s alleged injuries. The Court this time dismiss with prejudice. The TAC disregards the Court’s express limitations and instructions regarding the scope of permissible amendment and fails to state a claim for off-label marketing against Wyeth. Additionally, Plaintiff’s claims remain time-barred under all applicable statutes of limitations.

III. ARGUMENT

A. The TAC Improperly Exceeds the Scope of Permissible Amendment and Should Be Dismissed Under Fed. R. Civ. P. 41(b)

The TAC should be dismissed under the express terms of the Court’s Order, which provided that “[f]ailure to amend by the deadline in a manner consistent with the Court’s order will result in a dismissal under Federal Rule of Civil Procedure 41(b).” Order at 4 (emphasis added). Because the amendments in the TAC fail to give any new specifics and otherwise are not “consistent with the Court’s order,” the TAC should be dismissed under Rule 41(b).

The TAC violates the Order in multiple respects. First, despite the Order’s explicit instructions, Plaintiff amends and re-alleges his previously dismissed claims for failure to warn and failure to provide Plaintiff with a Medication Guide. Even though this Court has dismissed

those claims with prejudice, the TAC repeats allegations that Defendants failed to provide the “federally mandated” Medication Guide. Plaintiff alleges, for instance, that “Defendants engaged in a conspiracy to suppress material facts from Decedent that included, but was not limited to, *ensuring he did not receive a Medication Guide in the form and manner required by law*,” and that “due to this conspiracy...Decedent suffered harm.” TAC ¶ 14 (emphasis added); *see also* SAC ¶ 102 (containing nearly identical allegation); TAC ¶¶ 3, 21, 40, 42, 75, 86, 95, 96 (additional Medication Guide allegations).

Plaintiff attempts to recast his Medication Guide allegations as part of his off-label promotion claim, but the allegations are the same as those the Court has already dismissed. The TAC alleges that:

Defendants owed a duty to Decedent to market, cause to be distributed, and sell Amiodarone only for uses approved by the FDA and for uses for which it has been established as efficacious, and only when provided with the mandated Medication Guide in the form required by law....Defendants disregarded the risk of harm created by the marketing, distribution, and sale of Amiodarone for these “off-label” uses without the required Medication Guide.

TAC ¶ 75 (emphasis added). Plaintiff cannot simply repackage his Medication Guide allegations as an off-label promotion claim. By asserting that Defendants failed to comply with an alleged duty to provide the “mandated Medication Guide in the form required by law”—*i.e.*, FDA regulations—Plaintiff is simply re-pleading his flawed and preempted Medication Guide claims under the guise of off-label promotion. Regardless of the label, it is plain that Plaintiff is still improperly “hanging his hat on FDA regulations” to allege some dereliction of duty related to the Medication Guide, an approach the Court has already rejected. Order at 3.

The same is true for Plaintiff’s failure to warn allegations, which should have been removed from the TAC because they are not “claims based on...off-label marketing allegations only.” Order at 4. Again, Plaintiff tries to re-characterize his allegations about the warnings and labels for amiodarone as an element of his off-label marketing theory; however, in reality, the TAC continues to allege the inadequacy or inefficacy of the drug’s labeling, and that Defendants were obligated to “correct” the warning and labeling information that was made available by various third parties. For instance, Plaintiff alleges (albeit vaguely) that information provided by a

number of third parties about amiodarone was “false and misleading” and that Defendants had a duty to “correct” such information as part of the product’s labeling. *See, e.g.*, TAC ¶¶ 39-41; *see also id.* ¶¶ 35, 36, 79, 87, 94 (repeating allegations that Defendants were under a duty to “correct” inaccurate or misleading information disseminated by third parties). Plaintiff alleges that these supposedly “misleading ‘warnings’ or information...watered down the FDA-approved labeling and rendered the overall warnings inadequate.” *Id.* ¶ 41. These allegations, like those in the SAC, “contain[] echoes of the warning and labeling claim the Court dismissed with prejudice.” Order at 2. Plaintiff was prohibited from re-alleging such claims but did so anyway, ignoring the Court’s Order.

Not only does Plaintiff improperly re-plead claims that the Court has already dismissed with prejudice, but Plaintiff also alleges an entirely new cause of action for “Strict Liability – Manufacturing Defect.”² *See* TAC ¶¶ 91-100. The Court made clear that Plaintiff may not “add any new claims...without express leave of Court.” Order at 4. Plaintiff did not obtain or even request leave of Court to plead this new claim. Adding this cause of action without the Court’s leave blatantly disregards the Order and alone justifies dismissal under Rule 41(b) for failure to comply with the Order’s clear instructions.

Moreover, because this new claim is predicated entirely on FDA regulations, specifically, the FDA’s Good Manufacturing Practice for Finished Pharmaceuticals, 21 C.F.R. § 211, *et seq.*, it is improper for the reasons set out in the Court’s prior dismissal orders. *See* TAC ¶ 92. The Court has repeatedly found that claims based solely on federal regulatory requirements fail to state a claim for relief because they are preempted. *See* Order re Motions to Dismiss, Dkt. 76; Order at 2-3.

² The TAC does not differentiate between Wyeth as the brand innovator and Sandoz and Eon as the manufacturers of Decedent’s generic amiodarone in alleging the claim for “Strict Liability – Manufacturing Defect.” *See* TAC at 28. Wyeth suspects this may have been in error because strict products liability claims may only be asserted against the manufacturer of the product used or ingested by the allegedly injured party. *See, e.g., Brown v. Superior Ct.*, 44 Cal.3d 1049, 1056-57 (1988) (strict liability “holds the manufacturer [of the defective product] liable if the product was defective”); *Garcia v. Joseph Vince Co.*, 84 Cal. App. 3d 868, 876 (1978) (“A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being.”). Regardless, the claim still violates the Order and is grounds for dismissal under the Order and Rule 41(b).

Substantively, this new claim also improperly challenges the adequacy of the drug’s labeling and the Defendants’ alleged failure to ensure distribution of the Medication Guide, allegations the Court has dismissed with prejudice. Plaintiff alleges, for instance, that “[t]he Manufacturer Defendants either failed to follow appropriate written procedures regarding the labeling of Amiodarone or fail to have the required written procedures in place to ensure such labeling is both accurate and appropriately distributed.” TAC ¶ 94. As to the Medication Guide, Plaintiff alleges that “Defendants also failed to implement a safer alternative design for the delivery of the Medication Guide that would have prevented or significantly reduced the risk of the Decedent’s personal injuries and death,” and that “[t]he Manufacturer Defendants’ failure to ensure the Medication Guides were properly printed, affixed, distributed, and received are in violation of the FDA’s Good Manufacturing Practices regarding Packaging and Labeling Control.” *Id.* ¶¶ 95-96. Thus, not only has Plaintiff added a new cause of action that it had no right to plead, but that claim also improperly reasserts substantive allegations the Court has already dismissed on their merits, just under a different label. This is a thinly-veiled effort to resuscitate claims the Court has already dismissed with prejudice. These allegations, and thus the TAC as a whole, are not “consistent with the Court’s Order.” Order at 4. As the Court warned, this should result in dismissal under Rule 41(b). *Id.*

B. The TAC Fails to Allege Plaintiff’s Off-Label Promotion Claims With the Required Plausibility or Specificity

Even as to the claims the Court allowed to proceed, Plaintiff’s TAC simply tracks the deficient SAC, and thus still “wholly fail[s]” to address the lack of specificity that this Court has previously required. Plaintiff’s off-label marketing claims remain fatally defective and should be dismissed without further leave to amend. In the TAC, Plaintiff alleges that Wyeth “engaged in extensive, unlawful off-label [marketing] and overpromotion of Cordarone® as a first-line treatment for a-fib,” which “effectively nullified the efficacy of any warning labels for the drug and its generic version, Amiodarone.” TAC ¶ 5; *see also id.* ¶¶ 28-33. The Court has held that these claims “sound[] in fraud and consequently need[] to meet the heightened particularity standard under Federal Rule of Civil Procedure 9(b).” Order at 3. The Court has twice dismissed

1 Plaintiff's claims for off-label promotion for failure to "adequately allege facts for each element
2 of his claims against each defendant for the off-label marketing portion of his case," which
3 requires Plaintiff to "say much more about what, specifically, each defendant said and did, and
4 how those statements and actions (or lack thereof) relate[d] to plaintiff personally and to his
5 physician..." Order at 3-4.

6 The Court should do so again here because the TAC, like all prior iterations of Plaintiff's
7 complaint, fails to satisfy the heightened pleading requirements for fraud or even the plausibility
8 standard under Rule 8(a) and *Twombly* and *Iqbal*. Once again, Plaintiff does not provide any
9 specific facts about what Wyeth did (or did not do) in allegedly marketing the drug for off-label
10 uses, let alone tie such facts to Plaintiff personally or his physician. The only arguably "specific"
11 conduct by Wyeth alleged anywhere in the TAC is Wyeth's purported sponsorship of a
12 Continuing Medication Education ("CME") seminar in 1998, *fourteen years* before Plaintiff was
13 prescribed generic amiodarone. See TAC ¶ 30. This allegation has appeared in every version of
14 Plaintiff's complaint, including the recently dismissed SAC (at ¶ 58). There is no reason this
15 allegation would be sufficient now when it has failed to carry the day in every prior pleading
16 Plaintiff has filed.

17 Plaintiff still fails, for instance, to provide any specific facts showing that his physician
18 ever viewed or read any marketing material created, disseminated, or otherwise promoted by
19 Wyeth, let alone what such materials allegedly said, how the information was false or misleading,
20 or how it influenced a prescribing decision.³ Instead, Plaintiff simply repeats the generic
21 allegation that his physician "was a victim of Defendant Wyeth's long term and successful brand
22 innovator promotional efforts." TAC ¶ 23; *see also* SAC ¶ 30 (containing nearly identical
23 allegation). Rather than identify any specific facts related to Plaintiff or his doctor, the TAC

24 _____
25 ³ Nor has Plaintiff explained how reliance would have been *reasonable*, as California law
26 requires. See, e.g., *Samica Enters. LLC v. Mail Boxes Etc., Inc.*, 460 F. App'x 664, 665 (9th Cir.
27 2011) ("[I]t is well established that reasonable reliance is an element of common law fraud and
28 misrepresentation claims."). As a matter of law, it would not have been reasonable for a physician
in 2012 to rely on marketing materials from the 1980s and 1990s. See, e.g., *Lyman v. Pfizer, Inc.*,
No. 2:09-cv-00262, 2012 WL 2970627, at *19 (D. Vt. July 20, 2012) ("Between September 2003
and January 2007, any prescriber's reliance on statements made by Wyeth before 2002 . . . was
not justifiable.").

1 instead includes broad-sweeping allegations regarding the behavior of prescribing physicians
 2 generally and the sources of information they typically consult, which purportedly “misled and/or
 3 deceived physicians and the public, including Decedent and Decedent’s physician into believ[ing]
 4 Amiodarone was an appropriate and safe treatment for a-fib.” TAC ¶¶ 28-41, 46-49. But the
 5 practices of physicians generally and the information they may or may not have consulted
 6 concerning amiodarone have no bearing on what *Plaintiff’s doctor specifically* reviewed,
 7 understood, and relied on in prescribing amiodarone to Plaintiff. The TAC is still devoid of any
 8 particularized allegations that Plaintiff’s doctor relied on or was influenced in any way by
 9 anything Wyeth said, did, or failed to do.

10 Plaintiff, for instance, repeats the allegations that Defendants “marketed, promoted, and
 11 ‘pushed’ Amiodarone” for off-label uses by:

12 (1) authoring, directly and indirectly, various studies and articles touting
 13 Amiodarone as a treatment for A-fib; (2) sponsoring or funding various CME
 14 events attended by prescribing physicians, which included providing misleading
 15 and false materials to attendees; (3) providing false and misleading information to
 16 the publishers, developers and distributors of reference materials, such as the PDR
 17 and Epocrates and other compendia, used by physicians in prescribing situations;
 (4) causing representatives to visit prescribing physicians; (5) placing misleading
 information on websites and catalogs; (6) sponsoring trials, studies or surveys
 purporting to show Amiodarone as a viable treatment for A-fib; or (7) paying
 influential cardiologists to act as “opinion leaders” advocating the off-label use of
 Amiodarone.

18 TAC ¶ 32; *see also* SAC ¶ 132 (containing nearly identical allegations). But these allegations
 19 again fail to specify anything *Wyeth* (or any other Defendant) said or did, as required to state a
 20 viable off-label promotion claim. Nor does Plaintiff tie these alleged acts to Plaintiff personally or
 21 his physician. As the Court has repeatedly stated in dismissing the prior complaints, Plaintiff
 22 cannot state a claim for off-label promotion absent an alleged nexus between the generalized
 23 conduct purportedly attributable in some unspecified way to Wyeth and Plaintiff’s own
 24 prescription and ingestion of amiodarone. The TAC still fails to show any connection between
 25 any alleged conduct by Wyeth and Plaintiff or his prescriber.

26 Plaintiff also attempts to bolster his claim by expanding upon the generalized allegations
 27 in the SAC regarding the PDR and Epocrates by adding vague references to other third-party
 28 sources of prescription drug information—such as Electronic Health Record companies, social

1 networks for healthcare providers, online websites such as WebMD, the Mayo Clinic, and the
 2 American Heart Association, and other publications and apps. *See* TAC ¶¶ 37-39. But despite
 3 naming additional sources of prescription drug information, the substance of these allegations is
 4 unchanged from the SAC and remains overgeneralized and non-specific to Wyeth or any other
 5 Defendant. These allegations do not state “what, specifically, [Wyeth] said and did, and how
 6 those statements and actions (or lack thereof) relate to plaintiff personally and to his physician,”
 7 and thus do not satisfy the pleading requirements for fraud-based claims. Plaintiff does not
 8 specify any statements actually or even purportedly made by Wyeth, to which third-party
 9 providers such information allegedly was given, when or by whom they allegedly were made, or
 10 any other details of the alleged fraudulent conduct. *See, e.g., Neubronner v. Milken*, 6 F.3d 666,
 11 672 (9th Cir. 1993) (the “complaint must specify such facts as the times, dates, places, benefits
 12 received, and other details of the alleged fraudulent activity”); *Lee v. Wells Fargo Bank, N.A.*,
 13 5:12-cv 02820 EJD, 2013 WL 1117866, at *1 (N.D. Cal. Mar. 18, 2013) (“[T]he allegations must
 14 contain ‘an account of the time, place, and specific content of the false representations as well as
 15 the identities of the parties to the misrepresentations.’”) (citation omitted); *Tarmann v. State Farm*
 16 *Mut. Auto. Ins. Co.*, 2 Cal. App. 4th 153, 157 (1991) (“The requirement of specificity in a fraud
 17 action against a corporation requires the plaintiff to allege the names of the persons who made the
 18 allegedly fraudulent representations, their authority to speak, to whom they spoke, what they said
 19 or wrote, and when it was said or written.”). Nor does Plaintiff even articulate *how* the
 20 information on these third-party sites is supposedly false or misleading, or how it relates to
 21 Plaintiff and his physician, if at all.

22 In addition to being non-specific, Plaintiff’s allegations are also inconsistent and
 23 nonsensical. On the one hand, Plaintiff suggests that Defendants made misleading statements to
 24 the publishers of the PDR or Epocrates, by “directly or indirectly provid[ing] the indications and
 25 usage information regarding Amiodarone.” TAC ¶ 33; *see also* SAC ¶ 14. On the other hand,
 26 Plaintiff suggests that Defendants made no such statements but instead “willfully ignored the
 27 false and misleading information in Epocrates and the PDR” provided by others, “thereby
 28 concealing the truth about Amiodarone to physicians.” TAC ¶ 35; *see also* SAC ¶ 15. These

1 vague, inconsistent assertions, which are repeated nearly verbatim from the SAC, still fail to
2 satisfy both the heightened pleading requirements of Rule 9(b) and the plausibility requirements
3 of Rule 8(a) as set forth in *Twombly* and *Iqbal*.

4 Moreover, although Plaintiff has removed some of the remote and too-general allegations
5 regarding FDA enforcement actions against Wyeth from the 1980s, 1990s, and early 2000s,
6 Plaintiff has simply replaced them with even more generalized allegations regarding news reports
7 of overall amiodarone prescription activity, the practices of prescribing physicians generally, and
8 a variety of third-party sources available to physicians for prescription drug information. *See*
9 TAC ¶¶ 33-48. Accordingly, the TAC still “reads much more like a general investigative report
10 than an actionable complaint by this plaintiff for a specific injury attributable to these
11 defendants,” and thus fails to satisfy the basic pleading requirements of Rule 8(a) or heightened
12 requirements of Rule 9(b). Order at 4.

13 Finally, although Plaintiff appears to have broadened his allegations from the SAC
14 regarding adverse event reporting, the expanded allegations do not add any specific facts
15 regarding Wyeth’s alleged conduct in supposedly failing to report adverse medical events, nor any
16 specific allegations connecting the supposed underreporting of adverse events to Plaintiff or his
17 prescribing physician. *See* TAC ¶¶ 51-58. Plaintiff speculates, for instance, that “[b]ased on the
18 percentage of people diagnosed just with pulmonary toxicity, there would be tens of thousands of
19 adverse event reports submitted each year. Yet that does not appear to be even close to the
20 number of these reports submitted to the FDA in connection with Amiodarone.” *Id.* ¶ 54. This
21 speculation falls far short of the specific fact allegations necessary to state a claim for off-label
22 marketing.

23 It is plain after four rounds of pleading that Plaintiff cannot plead the necessary facts with
24 the necessary specificity to state a viable claim for off-label promotion against Wyeth. Plaintiff
25 has never come close to alleging the specific conduct by Wyeth, or the connection between any
26 specific actions and Plaintiff and his prescribing physician, that are required for this claim to
27 survive dismissal. This was Plaintiff’s “one last chance” to amend these claims to add the
28 required facts, and he has not done so. Accordingly, the TAC should be fully and finally

1 dismissed, with no further leave to amend.

2 **C. Plaintiff's Claims Remain Time-Barred**

3 Finally, Wyeth renews the arguments from its previous Motions to Dismiss the SAC and
 4 FAC that Plaintiff's claims are time-barred and must be dismissed. *See* Dkt. 49. Plaintiff admitted
 5 in his original complaint that he obtained a diagnosis of "amiodarone-induced pulmonary
 6 fibrosis" in September 2012, over three years before he filed this lawsuit, on March 15, 2016.
 7 Plaintiff's strict liability, negligence, and fraud and deceit causes of action are thus barred by the
 8 applicable two- and three-year statutes of limitations. *See* Cal. Civ. Proc. §§ 335.1, 340.8(a);
 9 *Viramontes v. Pfizer Inc.*, No. 2:15-cv-1754-TLN (AC) (PS), 2015 WL 9319497, at *6-7 (E.D.
 10 Cal. Dec. 23, 2015) (negligence and products liability claims subject to a two-year statute of
 11 limitations); Cal. Civ. Proc. §§ 338(a), (c)(1), and (d); *Minichino v. Wells Fargo Bank, N.A.*, No.
 12 C 11-01030 (SI), 2011 WL 4715153, at *6 (N.D. Cal. Oct. 7, 2011) (applying a three-year statute
 13 of limitations to fraud and deceit claims).

14 The TAC, like Plaintiff's previous complaints, invokes the "discovery rule" to purportedly
 15 toll the limitations period until Plaintiff allegedly discovered or had reason to discover that he had
 16 been injured. TAC ¶¶ 25-26; *Romo v. Wells Fargo Bank, N.A.*, No. 15-cv-03708 (EMC), 2016
 17 WL 324286, at *4 (N.D. Cal. Jan. 27, 2016) (citing *Lukovsky v. City & Cty. of S.F.*, 535 F.3d
 18 1044, 1048 (9th Cir. 2008)). Plaintiff alleges that, notwithstanding his diagnosis of "amiodarone-
 19 induced pulmonary fibrosis," "[t]he link between Decedent's injuries and Defendants' wrongful
 20 conduct was not discovered, and through reasonable care and due diligence could not have been
 21 discovered, until a date within the applicable statute of limitations." TAC ¶ 25. This is because,
 22 allegedly, "Decedent thought his development of pulmonary fibrosis was a rare reaction to the
 23 Amiodarone rather than a deadly complication of Amiodarone use that was known to Defendants
 24 to be a common complication of Amiodarone." *Id.* According to Plaintiff, discovering this
 25 information "would require a complex examination and analysis of various legal statutes and
 26 regulations, which is far beyond the knowledge or ability of a lay person." *Id.* ¶ 26.

27 Plaintiff continues to misunderstand the discovery rule. The rule does not require that the
 28 plaintiff know "the specific facts necessary to establish the cause of action," but rather only that

1 he have “notice or information of circumstances to put a reasonable person on inquiry.” *Norgart*
 2 *v. Upjohn Co.*, 21 Cal. 4th 383, 398 (1999). Plaintiff received such notice in August or September
 3 2012, when he was diagnosed with “amiodarone-induced pulmonary fibrosis.” This specific
 4 diagnosis informed Plaintiff of both the nature *and* the purported cause of his injuries. A
 5 reasonable person who obtained such a diagnosis and then experienced the health problems
 6 Plaintiff describes would have been on notice of a potential link between the amiodarone and the
 7 resulting health problems. TAC ¶ 24. The statute of limitations began to run once Plaintiff
 8 obtained this diagnosis. *See Jolly v. Eli Lilly & Co.*, 44 Cal. 3d 1103, 1110-11 (1988) (mere early
 9 suspicion of wrongdoing is sufficient to put plaintiffs on inquiry notice).

10 Nor is Plaintiff entitled to equitable tolling. *See* Dkt. 49; TAC ¶ 27. Equitable tolling
 11 provides relief from the statute of limitations in the event of a plaintiff’s “excusable ignorance
 12 and...lack of any prejudice to the defendant,” which takes into account plaintiff’s lack of actual
 13 or constructive notice of the time requirements or “extraordinary circumstances beyond [his]
 14 control” making it impossible to file in a timely manner. *M.O.R.E., LLC v. United States*, No. 12-
 15 cv-03609 (JST), 2015 WL 5093621, at *5-7 (N.D. Cal. Aug. 28, 2015) (citing *Seattle Audubon*
 16 *Soc’y v. Robertson*, 931 F.2d 590, 595 (9th Cir. 1991) (deeming war to be an extraordinary
 17 circumstance) and *Scholar v. Pac. Bell*, 963 F.2d 264, 267-268 (9th Cir. 1992) (noting a need for
 18 extreme circumstances)). The doctrine may turn on whether plaintiff has alleged “any acts on the
 19 part of defendants to prevent him from detecting the facts sufficient to support bringing his claims
 20 on a timely basis.” *Li v. Cty. of San Diego*, 259 F. App’x 912, 913 (9th Cir. 2007).

21 The TAC, like the prior complaints, alleges that the applicable statutes of limitations
 22 should be tolled “due to equitable tolling and the ongoing conspiracy among Defendants” to
 23 conceal the “true facts” about amiodarone through misleading marketing and omissions.
 24 TAC ¶ 27. But these allegations are foreclosed by Plaintiff’s own description of the diagnosis of
 25 “amiodarone-induced pulmonary fibrosis” he received in the fall of 2012. *See* Compl. ¶ 37.
 26 Plaintiff had clear, adequate notice at that time of a potential link between amiodarone and his
 27 “amiodarone-induced pulmonary fibrosis.” Plaintiff does not specify any extraordinary
 28 circumstances or specific conduct by Defendants that precluded him from initiating an action

1 after he received the amiodarone-related diagnosis. Plaintiffs' claims are untimely, which is a
 2 separate ground on which his claims can and should be dismissed, with prejudice.

3 **IV. CONCLUSION**

4 The Court's recent Order gave Plaintiff "one last chance" to amend his off-label
 5 marketing claims *only* and provided clear instructions regarding the scope of permissible
 6 amendment in any further amended pleading. That Order notwithstanding, Plaintiff's TAC
 7 improperly re-pleads claims and allegations that have already been dismissed with prejudice and
 8 states an entirely new claim without "express leave of Court," as required. Those failures alone
 9 are sufficient grounds for dismissal under the Court's Order and Fed. R. Civ. P. 41(b).

10 As to Plaintiff's off-label marketing claim, the TAC fails to add any new specifics.
 11 Instead, it simply repeats the deficiencies of Plaintiffs' prior pleadings by failing to provide any
 12 specific facts regarding what Wyeth (or any other Defendant) allegedly did or did not do, or any
 13 specific link between Wyeth's conduct and Plaintiff, his prescribing physician, or his ingestion of
 14 generic amiodarone. The TAC falls far short of the pleading requirements under Rule 8(a) and
 15 Rule 9(b) as articulated by the Court in its Order. As Plaintiff's "likely final opportunity to
 16 amend," Order at 1, the TAC should be dismissed, this time with prejudice.

17 Dated: July 24, 2019

18 **DLA PIPER LLP (US)**

19
 20 By /s/ George Gigounas
 21 GEORGE GIGOUNAS
 22 Attorneys for Defendant
 23 Wyeth Pharmaceuticals Inc.
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